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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.   | CONFIRMATION NO. |
| 10/563,657   | 05/18/2006  | Donald-Bane Stewart  | SPC601 (67316.000003) | 1723             |
| 29484  | 7590        | 08/31/2009           | EXAMINER              |                  |
| PATENTMETRIX<br>14252 CULVER DR. BOX 914<br>IRVINE, CA 92604 |             |                      | FLORY, CHRISTOPHER A  |                  |
|  |             |                      | ART UNIT              | PAPER NUMBER     |
|  |             |                      | 3762                  |                  |
|  |             |                      | NOTIFICATION DATE     | DELIVERY MODE    |
|  |             |                      | 08/31/2009            | ELECTRONIC       |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

hazim@patentmetrix.com  
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|                              |   |   |  |
|------------------------------|---|---|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/563,657    | <b>Applicant(s)</b><br>STEWART, DONALD-BANE |  |
|                              | <b>Examiner</b><br>CHRISTOPHER A. FLORY | <b>Art Unit</b><br>3762                     |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-32 and 34-55 is/are rejected.
- 7) ☒ Claim(s) 33 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/9/09; 5/6/09</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments, see section 4 on page 17, filed 6 May 2009, with respect to the §112 rejection of claim 23 have been fully considered and are persuasive. The §112 rejection of claim 23 has been withdrawn.

2. Applicant's remaining arguments filed 6 May 2009 have been fully considered but they are not persuasive. Claims 1-5, 27-29, 42 and 46-49 stand rejected under 35 U.S.C. 102(b) as being anticipated by Lovejoy'186. Claims 1-5, 24-29 and 42-49 stand rejected under 35 U.S.C. 102(b) as being anticipated Meij'967. Additionally, in light of the amendments as well as further consideration of the claims and prior art, new grounds of rejection are also presented.

3. Initially, it is noted that Applicant has amended several of the claims to read "axillary" line instead of "auxiliary" line. This is considered to be a change of scope since the meaning of "axillary" and "auxiliary" are clearly different. Furthermore the Specification does not appear to provide any support for the limitation of an "axillary line" as the Specification only makes reference to the different "auxiliary line."

4. Regarding claim 1, Applicant argues that convention requires the use of 10 electrodes to generate an ECG signal, and that therefore neither Lovejoy'186 nor Meij'967 discloses the ability to generate or synthesize ECG signals from less than 10 electrodes.

Regarding Lovejoy'186, it is noted that this limitation of less than 10 electrodes is explicitly supported since Lovejoy'186 discloses recording an ECG with "a plurality of at

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least 3 electrodes" (abstract) and refers to the collected ECG as simply a multi-lead ECG and not explicitly and only the standard 12-lead ECG requiring at least 10 electrodes. Therefore, certain embodiments of Lovejoy'186 clearly and explicitly record ECG data with less than 10 electrodes.

Regarding Meij'967, Meij'967 clearly discloses recording and synthesizing of ECG data from a minimum number of leads wherein the ECG data is specifically synthesized in instances where particular leads, including multiple leads, among the traditional 12-lead ECG are missing or not operating (Abstract; column 2, lines 42-51; column 10, lines 11-40), and thus clearly and directly reads on the argued limitation.

### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-29, 34-37, 42-49, 52, and 53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has amended the rejected claims to recite an "axillary" rather than "auxiliary" line. There is no support in the Specification or Figures for an "axillary" line, as the Specification only recites and

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refers to an "auxiliary" line. Since the two are clearly of different scope, correction is required.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 38 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 38 recites the limitations "said Vm site" and "said VnR site"" in line 2.

There is insufficient antecedent basis for these limitations in the claim.

### ***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-5, 27-29, 42 and 46-49 stand rejected, and claims 30-32, 34-36, 38, and 50-53 are rejected under 35 U.S.C. 102(b) as being anticipated by Lovejoy et al. (US 6,453,186, hereinafter Lovejoy'186).

Regarding claims 1, 30, 34-36, 38, 42 and 49-53, Lovejoy'186 discloses an apparatus and method of synthesizing ECG signals (title; abstract) comprising receiving signals from a first group of electrodes connected to predetermined locations on a body to acquire a first set of ECG signals and a further signal using a subset of the first set of

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signals, wherein the electrodes comprise the standard 2 lead electrode sites V2, V5, and V5R (column 4, line 12 through column 5, line 17). The limitation of less than 10 electrodes is explicitly supported since Lovejoy'186 discloses recording an ECG with "a plurality of at least 3 electrodes" (abstract) and refers to the collected ECG as simply a multi-lead ECG and not explicitly and only the standard 12-lead ECG requiring at least 10 electrodes. Therefore, certain embodiments of Lovejoy'186 clearly and explicitly record ECG data with less than 10 electrodes.

Further regarding claims 30, 34 and 38, it is noted that V<sub>c</sub> is merely recited as being placed on the sternum and carries no further special definition. Therefore, V1 and V2 as disclosed by Lovejoy'186 are considered to read on the limitation of V<sub>c</sub> since V1 and V2 are known to be located immediately adjacent the sternum in the 4<sup>th</sup> interstitial space (column 4, lines 13-32), and therefore are considered to be placed on the sternum.

Regarding claims 2-4, 32 and 38, Lovejoy'186 additionally discloses electrodes at RA and LA, or on the right and left side of the torso level with the limbs, or anywhere on the right and left sides of the body, in addition to V2, V5 and V5R (column 4, lines 57-63).

Regarding claims 5 and 31, Lovejoy'186 discloses electrode placement at the same height as the manubrium on the mid-clavicle line (column 4, lines 33-46).

Regarding claims 27-29 and 46, Lovejoy'186 discloses both storing and displaying the standard 12 lead ECG in real time (column 1, lines 13-19).

Regarding claim 47, Lovejoy'186 shows leads corresponding to each of the electrodes in Fig. 1.

Regarding claim 48, Lovejoy'186 shows the electrode patch being removable from the processing and storage means in Fig. 5,

12. Claims 1-5, 24-29 and 42-49 stand rejected, and claims 7-9, 11-15, 22, 30-32, 34-36, 38-40 and 50-55 are rejected, under 35 U.S.C. 102(b) as being anticipated by Meij et al. (US 6.690.967, hereinafter Meij'967).

Regarding claims 1, 7, 12, 14, 22, 30, 34-36, 38, 40, 42 and 49-55, Meij'967 discloses an apparatus and method of synthesizing ECG signals comprising receiving signals from a first group of electrodes connected to predetermined locations on a body to acquire a first set of ECG signals and a further signal using a subset of the first set of signals (title; abstract), wherein the electrodes comprise the standard 2 lead electrode sites V2, V5, and V5R (column 3, lines 27-46; column 4, lines 14-24; column 9, lines 27-33). Regarding Meij'967, Meij'967 clearly discloses recording and synthesizing of ECG data from a minimum number of leads wherein the ECG data is specifically synthesized in instances where particular leads, including multiple leads, among the traditional 12-lead ECG are missing or not operating (Abstract; column 2, lines 42-51; column 10, lines 11-40), and thus clearly and directly reads on the argued limitation.

Further regarding claims 7 and 12, and regarding claims 9, 18 and 39, Meij'967 is considered to disclose a temporary electrode that is connected at a different time than the first ECG set or equivalently activated only temporarily and then replaced upon selection of a different electrode subset (column 9, lines 34-52).

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Further regarding claims 22 and 40, Meij'967 discloses further detecting a subject's body posture and selecting or modifying the set of transformations on the basis of the body posture (column 11, lines 50-61; Fig. 6).

Further regarding claims 30, 34 and 38, it is noted that  $V_c$  is merely recited as being placed on the sternum and carries no further special definition. Therefore, V1 and V2 as disclosed by Meij'967 are considered to read on the limitation of  $V_c$  since V1 and V2 are known to be located immediately adjacent the sternum in the 4<sup>th</sup> interstitial space, and therefore are considered to be placed on the sternum.

Regarding claims 2-5, 31, 32 and 38, Meij'967 additionally discloses electrodes at RA and LA, or on the right and left side of the torso level with the limbs, or anywhere on the right and left sides of the body, in addition to V2, V5 and V5R (column 8, lines 27-41).

Regarding claims 8, 13 and 15, Meij'967 discloses generating a subject-specific transformation to act on the ECG signal to synthesize the temporary electrode signal (column 9, lines 38-41; column 12, lines 1-28; claims 1, 8, 17, 22 and 33).

Regarding claim 11, it is by definition inherent that the ECG signal of the temporary electrode is the potential difference between the electrode potential and the reference potential.

Regarding claims 24-26, Meij'967 discloses the method further comprising the calculation and application of a simulation matrix as described in the claim language (Figures 3 and 4 and related paragraphs).



Regarding claims 27-29 and 46, Meij'967 discloses both storing and displaying the standard 12 lead ECG in real time (Fig 4, database 110, screen 312 and related paragraphs).

Regarding claims 43 and 44, Meij'967 discloses a linear combination processing array (matrix 307) and a signal processor circuit under software control (preprocessor 104 or controller 308).

Regarding claim 45, Meij'967 shows separate units in Fig. 4.

Regarding claim 47, Meij'967 discloses leads corresponding to each of the electrodes (abstract).

Regarding claim 48, Meij'967 shows the electrode patch being removable from the processing and storage means (Fig. 1, memory 106).

### ***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 23 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meij'967.

Although Meij'967 does not expressly disclose that the body position sensor is one of an accelerometer, tilt sensor or manual switch, these sensing means used in conjunction with detecting posture or body position are well known in the art.

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***Allowable Subject Matter***

15. Claims 6, 10, 16-21, 33 and 37 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Specifically regarding claim 6, 33 and 37, the prior art is not found to disclose replacing the V2 electrode with a V<sub>c</sub> electrode that is specifically defined to be in a position on the sternum directly between standard electrode sites V1 and V2.

Specifically regarding claims 16 and 17, the prior art is not found to disclose a specific location for the temporary electrode on the right arm, shoulder or hand or left arm, shoulder or hand respectively.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Christopher A. Flory/

27 August 2009

**/George Manuel/**

Primary Examiner